2018 Current Fiscal Year Report: Bone, Reproductive and Urologic Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Bone, Reproductive and Urologic Drugs Advisory Committee	871

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	03/23/2018	03/23/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 3 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 3

Meetings and Dates

Purpose	Start	End
The committee discussed appropriate patient selection criteria and clinical trial design features, including acceptable endpoints, for demonstrating clinical benefit for drugs intended to treat interstitial cystitis and bladder pain syndrome. The committee also discussed whether bladder pain syndrome and interstitial cystitis reflect overlapping or different populations, and whether it is appropriate to assess efficacy in the same way for both conditions.	12/07/2017	12/07/2017
The committee discussed new drug application (NDA) 206089, oral testosterone undecanoate capsules, submitted by Clarus Therapeutics, for the proposed indication of testosterone replacement in males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired	01/09/2018	01/09/2018
The committee discussed new drug application (NDA) 208088, oral testosterone undecanoate capsules, submitted by Lipocine Inc. for the proposed indication of testosterone replacement in males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadotropism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).	01/10/2018	01/10/2018

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$13,548.00	$19,686.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$170,506.00	$173,228.00
18a(4). Personnel Pmts to Non-Member Consultants	$14,144.00	$16,405.00
18b(1). Travel and Per Diem to Non-Federal Members	$12,645.00	$17,589.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$20,200.00	$20,298.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$65,246.00	$66,156.00
18d. Total	$296,289.00	$313,362.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in obstetrics, gynecology, endocrinology, pediatrics, epidemiology, urology or statistics, and related specialties. The committee also will include one technically qualified member who is identified with consumer interests and may include one non-voting representative who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee held three meetings during FY-18. On December 7, 2017, the committee discussed appropriate patient selection criteria and clinical trial design features, including acceptable endpoints, for demonstrating clinical benefit for drugs intended to treat interstitial cystitis and bladder pain syndrome. The committee also discussed whether bladder pain syndrome and interstitial cystitis reflect overlapping or different populations, and whether it is appropriate to assess efficacy in the same way for both conditions. The committee members unanimously agreed that patients with interstitial cystitis and those with bladder pain syndrome be combined in clinical trials. Committee members noted that populations can be stratified and that symptoms for IC and BPS appear to be indistinguishable. Agency Action: The Agency is still reviewing recommendations that were made at the meeting. On January 9, 2018, the committee discussed new drug application (NDA) 206089, oral testosterone undecanoate capsules, submitted by Clarus Therapeutics, for the proposed indication of testosterone replacement in males for

conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). Members recognized the potential benefit of a safe and effective oral testosterone replacement therapy as another treatment option for men with classical hypogonadism. There was consensus that this product would likely be safe and efficacious for such men who are also at low cardiovascular risk but there was substantial concern about its safety if prescribed to large numbers of men with age-related hypogonadism, as was widely anticipated. Committee members who voted for approval (9 members) generally believed that the risks could be mitigated through measures such as a Risk Evaluation and Mitigation Strategy (REMS), labeling, and mandatory health care provider education. Members who voted “No” (10 members) were concerned that the scope of use outside of classical hypogonadism could lead to widespread harm in terms of cardiovascular risks. Agency Action: The Agency is still reviewing recommendations that were made at the meeting. On January 10, 2018, the committee discussed new drug application (NDA) 208088, oral testosterone undecanoate capsules, submitted by Lipocine Inc. for the proposed indication of testosterone replacement in males for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). Overall most of the committee members (13 out of 19) agreed that the benefit/risk profile of this product did not support approval as a testosterone replacement therapy. Committee members who voted “No, “stated that the existing uncertainties should be resolved before approval. Recommendations included a pre-approval ambulatory blood pressure monitoring study and further assessment of the potential for ex vivo conversion of testosterone undecanoate to testosterone. Committee members who favored approval were willing to resolve the uncertainties after approval, citing an unmet need for an oral testosterone product. Agency Action: The Agency is still reviewing recommendations that were made at the meeting. It is expected that the committee will meet 2 to 4 times in FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia, research, and/or clinical practice. Their advice and input lends credibility to regulatory decisions made and helps those decisions withstand intense public scrutiny. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

There were no reports required for this committee in FY-18.

Designated Federal Officer

Kalyani Bhatt Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Bauer, Douglas	09/22/2015	06/30/2022	Professor of Medicine and Epidemiology & Biostatistics, University of California San Francisco	Special Government Employee (SGE) Member
Burke, Ann	07/01/2016	06/30/2020	Associate Professor and Director, Family Planning, Johns Hopkins School of Medicine	Special Government Employee (SGE) Member
Dmochowski, Roger	09/22/2015	06/30/2019	Professor of Urology, Director of Pelvic Medicine and Reconstruction Fellowship, Vanderbilt University Hospital	Special Government Employee (SGE) Member
Drake, Matthew	09/22/2015	06/30/2019	Associate Professor of Medicine, Chair of Metabolic Bone Disease Core Group, Division of Endocrinology, Mayo Clinic College of Medicine	Special Government Employee (SGE) Member
Edwards, Beatrice	09/30/2016	06/30/2020	Associate Professor of Internal Medicine, University of Texas MD Anderson Cancer Center	Special Government Employee (SGE) Member
Gass, Margery	07/28/2017	06/30/2021	Consultant, Fred Hutchinson Cancer Research Center	Special Government Employee (SGE) Member
Lewis, Vivian	07/01/2014	06/30/2020	Vice Provost Faculty Development & Diversity, Professor, Obstetrics and Gynecology, University of Rochester	Special Government Employee (SGE) Member
Nahum, Gerard	03/31/2016	10/31/2019	Vice President of Global Development, General Medicine, Bayer HealthCare Pharmaceuticals, Inc	Representative Member
Pavlovich, Christian	07/28/2017	06/30/2021	Director of Urology & Oncology Johns Hopkins Bayview Medical Center, Baltimore, MD.	Special Government Employee (SGE) Member
Shaw, Pamela	07/28/2017	06/30/2021	Professor of Biostatistics, University of Pennsylvania School of Medicine	Special Government Employee (SGE) Member
Sorscher, Sarah	09/22/2015	06/30/2018	Deputy Director of Regulatory Affairs Center for Science in the Public Interest (CSPI)	Special Government Employee (SGE) Member

Number of Committee Members Listed: 11

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products;

establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Advisory Committee for Reproductive Health Drugs supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investgational human drug products for use in the practice of obstetrics, gynecology, and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Bone, Reproductive and Urologic Drugs Advisory Committee

enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
30

Number of Recommendations Comments
The committee made 30 recommendations from FY-03 through FY-18.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
80%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
It usually does. Product approval issues are first released to the sponsor. When

appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	✓
Reallocated resources	
Issued new regulation	✓
Proposed legislation	
Approved grants or other payments	
Other	✓

Action Comments

FDA approves or chooses not to approve an investigational new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A